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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,007	04/10/2001	Jeanette D. Rasche	EAMC00-09 01	9567

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OFFICE OF THE STAFF JUDGE ADVOCATE
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
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EXAMINER
SOTOMAYOR, JOHN

ART UNIT	PAPER NUMBER
3714	

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/829,007	Applicant(s) RASCHE ET AL
	Examiner John L Sotomayor	Art Unit 3714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 April 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

New corrected drawings are required in this application because the margins on figures 9A, 9B and 10 do not meet standard requirements. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5, 10 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are directed toward a means of "educating the user about asthma" as recited in claim 5, and a method of "educating the user about asthma" as recited in claims 10 and 21. The means or method of accomplishing the educational task is unclear thus rendering the claims indefinite.

3. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This claim is dependent upon claim 10 and inherits the deficiencies of that claim.

4. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This claim is dependent upon claim 21 and inherits the deficiencies of that claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1, 4-8, 10, 12-18, 20-31 and 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Finkelstein et al (US 6,283,923).

7. Regarding claim 1, Finkelstein et al discloses a means for questioning the user (Col 3, lines 30-33), means for accumulating a score based on answers to the questions (Col 8, lines 55-60), means for correlating the score to at least one indicator level (Col 6, lines 51-55) and means for informing the user of the results (Col 3, lines 40-43).

8. Regarding claim 4, Finkelstein et al discloses that a summary containing the answers to the questions and the indicator level is provided (Col 7, lines 21-36).

9. Regarding claims 5, 10 and 21, Finkelstein et al discloses a system designed to educate a user about asthma (Col 3, lines 17-20).

10. Regarding claim 6, Finkelstein et al discloses a method for repeating the test (Col 4, lines 45-50), a method for asking a question and receiving an answer and providing results to the user (Col 3, lines 29-43), incrementing a score based on the answers to the questions (Col 8, lines 55-60), and correlating the score to the at least one indicator level (Col 6, lines 51-55).

11. Regarding claim 7, Finkelstein et al discloses a system that informs the user of at least one indicator level (Col 3, lines 17-20).

12. Regarding claim 8, Finkelstein et al discloses a system in which an indicator such as alert level may be changed dynamically (Col 7, lines 11-14).

13. Regarding claims 12 and 27, Finkelstein et al discloses a system with software to perform asthma testing and education through a display in communication with a network (Col 3, lines 2-20).

14. Regarding claims 13 and 28, Finkelstein et al discloses a method of storing valid test data including answers and indicator information (Col 6, lines 25-30).

15. Regarding claims 14-15, and 25, Finkelstein et al discloses a monitoring system connected via network connection for performing the method of asthma testing and education through software based instructions (Col 4, lines 19-27).

16. Regarding claim 16, Finkelstein et al discloses a method for assessing severity of asthma for a patient by transmitting a question and receiving an answer and providing results to the user (Col 3, lines 29-43), accumulating a score based on the answers to the questions (Col 8, lines 55-60), and repeating the testing and scoring steps for all questions in a series of questions (Col 4, lines 45-50).

17. Regarding claim 17, Finkelstein et al discloses a method for storing a series of answers in a database (Col 6, lines 25-30).

18. Regarding claim 18, Finkelstein et al discloses a method for transmitting relevant patient background information and receiving answers for questions concerning the background patient information (Col 3, lines 6-8).

19. Regarding claim 20, Finkelstein et al discloses a method that provides a summary of the assessment to the individual (Col 4, lines 41-45).

20. Regarding claim 22, Finkelstein et al discloses that indicator material may be dynamically tailored to the needs of a particular patient (Col 7, lines 11-14).

21. Regarding claims 23-24, Finkelstein et al discloses that information concerning asthma may be provided to a patient by a physician based upon the patient's indicator scores (Col 7, lines 34-37).

22. Regarding claim 26, Finkelstein et al discloses a computer-readable medium having computer-executable instructions for asthma testing and education (Col 6, lines 50-55).

23. Regarding claim 29, Finkelstein et al discloses a networked apparatus for assessing a patient's asthma comprising an interface (Col 4, lines 28-29), a database including questions relating to asthma (Col 6, lines 29-36) and a calculator and assessor in communication with the interface (Col 6, lines 50-55).

24. Regarding claim 30, Finkelstein et al discloses that the interface is a graphical user interface and, thus, contains a graphical component (Col 4, lines 28-29).

25. Regarding claims 31 and 34, Finkelstein et al discloses a system that contains multiple databases on the decision support server for the storage of indicator and test data as in claim 31, and storage of predetermined criteria and indicator information as in claim 34, each of which is in communication with the system (Col 6, lines 25-36).

26. Regarding claim 33, Finkelstein et al discloses an apparatus for use with a system that has a processor, memory, display, input device, Graphical User Interface, multiple databases and calculation and assessment routines that are run by the processor (Col 4, lines 19-50).

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

30. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkelstein et al.

31. Regarding claim 9, Finkelstein et al discloses multiple scores and indicators (Col 7, lines 8-20), but does not specifically disclose that the indicator levels include severity level, compliance level, and performance level. However, Finkelstein et al does discuss providing a score for severity level (Col 6, lines 19-20) as one of the indicators for which a score is accumulated. Finkelstein et al also discusses issues of compliance and performance that are discussed between a patient and doctor as a result of the system asthma testing (Col 7, lines 21-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide an ability to provide indicators that include severity level, compliance level and performance level to provide better asthma information to the user.

32. Regarding claim 19, Finkelstein et al discloses a method of receiving answers to questions at the decision support server (Col 6, lines 65-68), which are then used to formulate alert status from background information. These alert status parameters may be changed dynamically to personalize them to a particular patient as a result of the answers received to assessment questions (Col 7, lines 1-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a means for personalizing the questions asked of individual patients in order to form personalized status alerts in a dynamic fashion.

33. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkelstein et al in view of Brown et al (US 5,879,163).

34. Regarding claim 2, Finkelstein et al discloses the accumulation of multiple scores for multiple indices (Col 7, lines 8-20), but does not specifically disclose randomizing the order of the questioning asked by the system. However, Brown et al (163) teaches a questionnaire

generator to allow users of the system to design and implement questionnaires for accumulating answers to health related questions (Col 4, lines 53-64). The Examiner takes official notice that an individual who is composing a questionnaire may place questions in any order, including a random order. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to allow questions to be placed in random order when utilizing the means of questionnaire generation and for accumulating multiple scores for multiple indicators. Modifying the system disclosed by Finkelstein et al with the questionnaire generator as taught by Brown et al (163) may provide for a better physician's treatment plan for a particular patient by optimizing the questions asked and indicator scores recorded.

35. Regarding claim 3, Finkelstein et al discloses multiple scores and indicators (Col 7, lines 8-20), but does not specifically disclose that the indicator levels include severity level, compliance level, and performance level. However, Finkelstein et al does discuss providing a score for severity level (Col 6, lines 19-20) as one of the indicators for which a score is accumulated. Finkelstein et al also discusses issues of compliance and performance that are discussed between a patient and doctor as a result of the system asthma testing (Col 7, lines 21-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide an ability to provide indicators that include severity level, compliance level and performance level to provide better asthma information to the user.

36. Claims 11 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkelstein et al in view of Brown (US 6,375,469).

37. Regarding claim 11, Finkelstein et al discloses that a user is provided with asthma education through a display in communication with a network (Col 3, lines 2-20). Finkelstein et

al does not specifically disclose that the educational material is presented in a multimedia form. However, Brown (469) teaches that educating users may be accomplished by providing personalized health information to users through a display device and a multimedia processor (Col 3, lines 22-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide educational material to users of the system in a multimedia format. Modifying the system set forth by Finkelstein et al with the system taught by Brown (469) provides vital health information to the user in an entertaining form and format over a network.

38. Regarding claim 32, Finkelstein et al discloses multiple databases for the storage of question, answer and indicator information (Col 6, lines 29-30). Finkelstein et al does not specifically disclose that the information disseminated from a database is educational information. However, Brown (469) teaches that health information intended to educate the user may be stored in a database of multimedia messages (Col 5, lines 42-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide educational material to users of the system from a database of such material. Modifying the system disclosed by Finkelstein et al with the teaching of Brown (469) provides a robust, entertaining means for supplying educational material concerning health issues, including asthma.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John L Sotomayor whose telephone number is 703-305-4558. The examiner can normally be reached on 7:30-4:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Hughes can be reached on 703-308-1806. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7768 for regular communications and 703-308-7768 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-4558.

jls
September 23, 2002

Joe H. Cheng
Primary Examiner